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## **Clinical performance of indirect composite onlays and overlays: 2-year follow up**

Özsoy, Alev ; Kuşdemir, Mahmut ; Öztürk-Bozkurt, Funda ; Toz Akalın, Tuğba ; Özcan, Mutlu

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## **Clinical performance of indirect composite onlays and overlays: 2-year follow up**

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**Short title:** *Clinical performance of indirect composite restorations.*

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**Abstract:** This prospective clinical trial evaluated the clinical performance of indirect onlay and overlay restorations made of resin composite. From January 2012 to March 2013, a total of 60 patients (36 males, 24 females; mean age;  $34.4 \pm 10$  years) received 67 posterior onlay/overlay restorations in the maxilla or mandible made of laboratory processed indirect composite (Gradia, GC, Japan). Patients were followed until March 2015. Two operators luted all restorations adhesively (Variolink II). Two independent calibrated examiners evaluated the restorations at baseline (2 weeks), 6 months, and then annually, during regularly scheduled maintenance appointments, using the modified USPHS criteria for anatomic form, marginal adaptation, color match, surface roughness, marginal discoloration, secondary caries, and postoperative sensitivity. The observation periods involved 4 recalls during 24 months. Changes in the USPHS parameters were analyzed with the Friedman and Bonferroni-adjusted Wilcoxon signed-ranks tests ( $\alpha=0.05$ ). The mean observation period was 24.1 months. All restorations assessed were clinically acceptable with alfa scores predominating. Two restorations failed due to severe pain and subsequent extraction during the observation period. Not the color match ( $p>0.05$ ) but marginal adaptation ( $p<0.05$ ), marginal discoloration ( $p<0.05$ ) and surface roughness ( $p<0.05$ ) showed a significant difference between baseline and the 2-year recall. No secondary caries or fractures were observed until the final follow up. The indirect composite tested demonstrated to be successful for posterior onlay and overlays but deteriorations in qualitative parameters were observed during the 2-year clinical service.

**Keywords:** Clinical trial, Gradia, indirect restoration, onlay, overlay, USPHS

## Introduction

The search for the ideal restoration material resulted in the development of new restorative materials and methods that meet the clinical requirements and expectations of the patients. Esthetic alternatives to cast-gold inlays and amalgam restorations today include direct composites, composite inlays, and ceramic inlays [1]. Color, brightness, good surface texture, longevity, and low cost are important parameters from the patient perspective.

Ceramic materials are brittle, with relatively high compressive but low flexural strength and fracture toughness [2,3]. Also, a high potential for wearing the enamel or resin restoration of the antagonist teeth is a major disadvantage of ceramic restorations. On the other hand, studies on direct resin composite restorations have confirmed their limited utility due to abrasion, fractures [4,5], disintegration [6], and secondary caries [7] after about 4 years of service. In an attempt to overcome the major limitations of ceramic materials and direct resin composites, new polymeric restorative materials have been introduced for indirect applications [8,9]. These materials present mechanical characteristics very similar to the dental structure, resulting in favorable distribution of occlusal loads in posterior teeth, with a lower potential for wearing the antagonist tooth. The process of laboratory polymerization facilitates the improvement of conversion degree, yielding to the best possible mechanical properties [10]. The processing methods are simpler and more cost effective than those for the ceramic restorations.

One such indirect resin composite (Gradia, GC, Tokyo, Japan) contains micro-fine ceramic pre-polymer filler with urethane dimethacrylate matrix, producing exceptionally high strength, wear resistance and superior polishability for crowns and bridges, inlays, onlays, and veneers [11]. The mechanical properties of some other indirect resin composites are inferior compared to ceramics in some clinical situations but they are claimed to absorb more of the occlusal stress [12].

The longevity and success of such indirect resin composite restorations depend on the correct indication, clinical experience of the operator, and accurate work by the laboratory technician [13]. Since limited number of long-term clinical studies exist under controlled conditions on the durability of adhesively luted indirect resin composite inlays/onlays [14-16], this study assessed the clinical performance of onlays and

overlays made of such resin composite longitudinally over 24 months. The tested null hypothesis was that evaluation criteria for the tested indirect composite would not deteriorate significantly up to 2 years follow up.

## **Materials and Methods**

The brands, manufacturers, chemical composition and batch numbers of the materials used in this study are listed in Table 1.

### **Study design**

Ethical committee of Istanbul Medipol University approved this clinical study (10840098-137). Patient were given written informed consent to participate before treatment and agreed to a recall program at baseline (15 days), 6 months, and thereafter annually.

#### **Inclusion and exclusion criteria**

Patients in need of removal of old large amalgam restorations or having extensive caries lesions were recruited in the study. Inclusion and exclusion criteria were as follows:

Adults of at least 18 years of age, with good oral hygiene, having at least two primary approximal caries in the posterior teeth having an antagonist tooth in occlusion, being mentally in good state to provide written consent to participate in the clinical study and willing to attend the scheduled follow-up appointments. Exclusion criteria included presence of teeth with severe periodontal problems, high caries risk and bruxism.

#### **Placement of restorations**

From January 2012 to March 2013, two operators with experience in adhesive dentistry, more than 15 years since graduation, made the cavity preparations and placed 67 posterior onlays/overlay restorations in the maxilla or mandible made of laboratory processed indirect composite (Gradia, GC) in a total of 60 patients (36 males, 24 females; mean age;  $34.4 \pm 10$  years). One dental technician fabricated all restorations.

Cavities were prepared according to common principles, which included an occlusal reduction of 1.5-2 mm with a wide isthmus and rounded occlusal-axial angles, and an axial wall of 1.5 mm in thickness. Where possible, the gingival margins were prepared entirely in enamel at the cemento-enamel junction. Cavities for overlays included both buccal and lingual/palatinal cusps. Both cavity types (onlays and overlays) were prepared with rounded internal angles, with a divergence of 6-15° between the walls and margins with 90° cavosurface.

Full-arch impressions were made with a single impression/double mixing technique using polyether material (Impregum Penta H Duosoft, 3M ESPE, Minn, USA). The cavity preparations were provisionalized for 1 week with photo-polymerized provisional material (Clip, Voco, Cuxhaven, Germany).

After adjustment when needed, the restorations were luted adhesively under rubber dam, employing total-etch system. The prepared teeth were initially cleaned with pumice slurry and etched with 35% phosphoric acid gel (Ultra-etch, Ultradent, South Jordan, UT, USA). The dentin adhesive system (Syntac Classic, Ivoclar Vivadent, Liechtenstein) was then applied uniform and gently air thinned. The internal surface of the restorations were silanized (Monobond S, Ivoclar Vivadent), waited for its reaction for 60 s and the solvent was evaporated with oil-free compressed air.

The onlays and overlays were luted adhesively with high-viscosity resin cement (Variolink II, Ivoclar Vivadent). Excess cement was removed occlusally with a brush and interproximally with dental floss. Prior to polymerization, the luting composite was covered with glycerin gel to prevent formation of oxygen-inhibited layer. Luting agent was photo-polymerized for 40 s from each direction for a total of 160 s using an LED device (Elipar DeepCure-S LED Curing Light, 3M ESPE) with light density of 1470 mW/cm<sup>2</sup> and wavelength of 430-480 nm from different positions. After photo-polymerization, rubber dam was removed and occlusal adjustments were made.

Patients were given routine oral hygiene instructions and asked to contact the clinician if they perceive any problems with the restored teeth.

Evaluation

Two specialist dentists who were blinded to the study groups, evaluated the restorations. In cases of different scores, the observers re-evaluated the restorations and reached a consensus. At baseline (1 week following restoration placement for evaluation of postoperative sensitivity), 6 months, and for final recall, the restorations were evaluated using modified United States Public Health Service (USPHS) criteria [17] for the following parameters: anatomical form, marginal adaptation, color match, surface roughness, marginal discoloration (staining of the luting cement), caries, and post-operative sensitivity (Table 2). The evaluated restorations were categorized “Perfect; No deteriorations observed” as “Clinically acceptable: Restoration had a minor defect and correction was possible without damaging the tooth or the restoration” or “Clinically unacceptable: Restoration had many defects and correction was impossible”. Patient acceptance was also recorded using a self-administered questionnaire.

#### Statistical analysis

Statistical analysis was performed using SPSS 21.0 software for Windows (SPSS Inc., Chicago, IL, USA). Friedman test was used to analyze changes in the follow-up scores of the restorations compared to baseline. *Post hoc* analyses were made using Bonferroni-adjusted Wilcoxon signed-ranks tests. P values less than 0.05 were considered to be statistically significant in all tests.

## Results

The distribution of 67 restored teeth and restoration types in the maxilla and mandible are presented in Table 3.

All patients (100%) attended the final recall visit. The mean observation period was 24.1 months.

Two teeth were extracted due to persistent severe pain. Marginal adaptation and marginal discoloration (n=8) scores were significantly different at 6 months, 1-year (n= 10), 2-year (n=11) recalls compared to baseline measurements ( $p<0.05$ ) (Table 4). Similarly, deteriorations in surface roughness scores increased over time being significantly different compared to baseline measurements ( $p<0.05$ ) (Table 5).

As for colour change, 6 restorations received Score 1 at the baseline and this number increased to 10 at the 1- and 2-year recalls. Color match were not statistically different ( $p>0.05$ ) compared to baseline (Figs.1a-c).

At baseline, all restorations were scored as perfect (Score 0) but 5 restorations were downgraded to “clinically acceptable” at the 6-months and 7 restorations at the end of the 2-years` recall.

No secondary caries or fractures were observed until the final follow up.

All patients reported positive outcomes regarding the colour of their restoration (Table 6).

## **Discussion**

This study evaluated the clinical performance of indirect resin composite (Gradia) for onlays and overlays placed in premolar and molars. Based on the results of this study, since marginal discoloration, adaptation and surface roughness parameters deteriorated over time significantly, the null hypothesis is rejected.

The continued evolution of adhesive technologies and materials has increased the application of resin composite materials for the direct and indirect restorations for the posterior dentition [18]. Onlay and overlay type of indirect restorations presenting large material loss, especially in endodontically treated posterior teeth, could be considered a conservative option through which post and core and crowns could be avoided. From cavity design perspective, onlay type of preparation covering at least one cusp is considered to protect the tooth structures better than the inlay design [19]. Indirect overlays and onlays provide good control of anatomical form and proximal contact compared to direct resin composites [20,21].

In this clinical study, no mechanical (chipping or fracture) or biological (caries) failures were observed but two of the restored teeth resulted in severe pain, and failed due to extraction during the 2 years follow up. From the qualitative perspective, the resin composite was stable in colour but marginal discoloration, adaptation and surface roughness parameters changed significantly up to 2 years of clinical service. The longevity of dental restorations depends highly on patient, material, and clinician related factors [22]. It is important to distinguish between early failures (after few weeks or few months), from medium time frame (6-24 months) and late failures (after 2 years or more) [23]. Early failures could be related to severe



treatment faults, incorrect indication, allergic/toxic adverse effects, or postoperative symptoms. Failures in the medium time frame are typically attributed to cracked tooth syndrome or tooth fracture, marginal discoloration, restoration staining or chipping, and loss of vitality [23]. Late failures on the other hand are predominantly caused by bulk fractures of the restoration or the tooth, secondary caries, endodontic complications, wear, deteriorations in the restoration material, or periodontal problems [24]. In this study, 2 of 67 restorations, one which was an onlay and the other an overlay, failed due to postoperative symptoms in the medium time frame. Such restorations are luted to deep cavities that carry the risk of thin dentin thickness close to the pulp.

The main reason for failure in inlays luted with dual-polymerized composite or conventional glass-ionomers were partial fracture or total loss of the inlays [25]. In one study, fractures in ceramic restorations were reported to occur typically during the first 6 to 8 months [26]. Bulk fracture in ceramic inlays and onlays are considered one of the most frequent causes of restoration failure [27], which is attributed to poor material properties, insufficient degree of conversion of the resin cement under the inlay or insufficient material thickness [28]. In this present study, no fractures or chippings were observed in any of the restorations. Care should be exercised during adequate preparation and occlusal adjustment of the restoration to avoid mechanical failures with both ceramic and composite restorations. Survival of the restorations on vital teeth showed significantly less failures than those on non-vital teeth [29]. Nevertheless, endodontic treatment and crown indication, which would necessitate endodontic treatment, post and core fabrication could be avoided largely in particular with overlays on large cavities.

The results of this study clearly demonstrated the major problem at the margins between the restoration and the tooth. According to the marginal adaptation analysis, four restorations received Score 1, and three restorations Score 2 at 2 year follow up. In this study, significant deterioration of marginal integrity and a significant increase in marginal discoloration were observed when baseline and 2-year data were compared. This might have been caused by insufficient bonding to the enamel or by degradation of the luting agent due to fatigue. Thus, it is important to achieve adequate adaptation to the remaining tooth structure, including edges and external cavosurface margins [30]. The negative results observed for

marginal adaptation, marginal discoloration and surface roughness occurred mainly in the first months and tended to remain at the same level until the final analysis. Similar observations were made with indirect ceramic restorations [31,32]. This indicates that the main concerns with this type of restorations should focus on the initial adaptation and importance of the cementation stage which may cause changes at the margins already during the first months of clinical service [33,34].

Marginal discoloration was detected in eleven cases at the end of 2 years; seven of these were rated with Score 1, and four with Score 2. This result could be related to the resin composite luting cement [35,36]. Since restorations are inserted into cavities using resin cement, the luting gap is always susceptible to increased wear. Loss of marginal integrity and Scores of 2 observed already at baseline is often due to polymerization shrinkage or removal of cement with instruments from the margins. Solubility of the resin matrix in composite resins takes place in the oral environment yielding to changes in the restoration-tooth interface [37,38]. Also, a critical factor is the polymerization shrinkage of the indirect composite resin used for the onlays and overlays [39]. Thus, it is possible that discoloration will continue to increase along with marginal disintegration. Likewise, compared with baseline, surface roughness also increased over time in this study. However, the majority of the patients judged their onlays/overlays to be 'very good' or 'good' in terms of surface texture at recall examinations. This indicated that a slightly rough surface did not cause discomfort to the patients, and they were mostly unaware of the pitted and slightly rough surfaces detected by the evaluators.

It is not easy to achieve a good colour match when the restoration is placed on an endodontically treated tooth, which causes already some mismatch at baseline. Crown discoloration after endodontic treatment is a common esthetic problem particularly for anterior teeth. The main causes of intrinsic crown discoloration related to endodontic treatment are disintegration of necrotic pulp tissue, hemorrhage into the pulp chamber, root canal filling materials [40-43]. ]. Yet, in this regard 58% of the patients evaluated the color as 'very good' and 32% 'good'.

Secondary caries is the most frequently cited reason for failure of dental restorations in general practice [44] and it affects up to 50% of all operative dentistry procedures delivered to adults [45]. Some studies have suggested that an increase in marginal gap size may result in degradation of the adhesive bond, in turn leading to microleakage and secondary caries [46]. After an evaluation period of 24 months, no secondary caries was found around the onlays and overlays in this study, even though most of the restorations presented deep cavity finish lines in dentin. Similarly, in previous studies, no secondary caries was observed in 50 inlay restorations over 34 months [47] and with inlays/onlays up to 1 and 5 years of observations [48,49].

The observation period of 2 years could be considered as the limitation this study but some significant clinical alterations were observed already at mid-term period. Patients with caries, bruxism or those having parafunctions have been excluded in this study, which might have positively affected the results. The performance of the tested material should also be observed in patients involved in risk groups. The restorations are currently being followed for long-term observations.

## **Conclusions**

From this study, the following could be concluded:

1. The indirect resin composite material (Gradia), tested for onlays and overlays for large cavities in the posterior region did not present any mechanical (chipping or fracture) or biological (caries) failures but two of the restored teeth presented severe pain and yielded to extraction during the 2 years follow up.
2. The qualitative analysis of the resin composite was stable in colour but suffered mainly from marginal discoloration, adaptation and roughness up to 2 years of clinical service. Yet, patients were highly satisfied.

**Clinical Relevance**

Although 2 year follow up could be considered rather short term, the tested indirect resin composite onlays and overlays performed well for restoring large posterior cavities, providing that except for colour stability, marginal discoloration, adaptation and roughness declined over time.

**Conflict of interest**

The authors did not have any commercial interest in any of the materials used in this study.

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## Captions to tables and figures:

### Tables:

**Table 1.** Brands, types, chemical compositions and manufacturers of the main materials used in this study.

**Table 2.** Modified United States Public Health Service (USPHS) Criteria.

**Table 3.** Distribution of restored teeth in the maxilla and mandible.

**Table 4.** Results of the clinical evaluation (modified USPHS scores, %) at baseline and at 6-month, and 1- and 2-year follow-up.

**Table 5.** Frequency distribution of scores for the restorations based on the modified USPHS criteria.

\*Different superscripts in one coloumn indicate statistically significant difference ( $p < 0.05$ ).

**Table 6.** Frequency of scores for patient satisfaction (%) at the 2-year recall examination.

### Figures:

**Figs. 1a-c** Representative photos of an overlay on the right 1<sup>st</sup> maxillary molar **a)** initial situation after endodontical treatment, **b)** baseline situation and **c)** at 2 years.

**Tables:**

<b>Brand</b>	<b>Type</b>	<b>Chemical composition</b>	<b>Manufacturer</b>
<b>Gradia</b>	Indirect resin composite	Matrix: UDMA, EDMA Filler: silica powder, silicate glass powder, prepolymerized filler (75 wt%)	GC Europe, Tokyo, Japan
<b>Ultra-etch</b>	Etching gel	35% phosphoric acid	Ultradent, South Jordan, Utah, USA
<b>Syntac</b>	Four-step etch-and-rinse adhesive	Etchant: 36% phosphoric acid Primer: Maleic acid, TEGDMA, water, acetone Adhesive (2 <sup>nd</sup> primer): Polyethyleneglycol dimethacrylate glutaraldehyde, water Heliobond: bis-GMA, TEGDMA, UDMA	Ivoclar, Vivadent, Schaan, Liechtenstein
<b>Variolink II</b>	Luting resin composite	Base: bis-GMA, UDMA, TEGDMA, fillers, ytterbium trifluoride, stabilizers, pigments, benzoyl peroxide	Ivoclar, Vivadent

**Table 2.** Brands, types, chemical compositions and manufacturers of the main materials used in this study.

Category and score	Criteria
<b>Anatomic form</b>	
0 (clinically acceptable)	Restoration is contiguous with tooth anatomy
1 (clinically acceptable)	Slightly under or over contoured restoration; marginal ridges slightly under contoured; contact slightly open (may be self-correcting); occlusal height reduced locally.
2 (clinically acceptable)	Restoration is under contoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced; occlusion affected
3 (clinically unacceptable)	Restoration is missing or traumatic occlusion; restoration causes pain in tooth or adjacent tissue
<b>Marginal adaptation</b>	
0 (clinically acceptable)	Restoration is contiguous with existing anatomic form; explorer does not catch
1 (clinically acceptable)	Explorer catches, no crevice into which explorer will penetrate is visible
2 (clinically acceptable)	Crevice at margin, enamel exposed
3 (clinically unacceptable)	Obvious crevice at margin, dentin or bas exposed
4 (clinically unacceptable)	Restoration mobile, fractured, or missing
<b>Color match</b>	
0 (clinically acceptable)	Very good color match, restoration almost invisible
1 (clinically acceptable)	Good color match
2 (clinically acceptable)	Slight mismatch in color, shade, or translucency
3 (clinically unacceptable)	Obvious mismatch, outside normal range
4 (clinically unacceptable)	Gross mismatch
<b>Marginal discoloration</b>	
0 (clinically acceptable)	No discoloration evident
1 (clinically acceptable)	Slight staining, can be polished away
2 (clinically acceptable)	Obvious staining, cannot be polished away
3 (clinically unacceptable)	Gross staining
<b>Caries</b>	
0 (clinically acceptable)	No evidence of caries contiguous with margin of restoration
1 (clinically unacceptable)	Caries is evident contiguous with margin of restoration
<b>Surface roughness</b>	
0 (clinically acceptable)	Smooth surface
1 (clinically acceptable)	Slightly rough or pitted surface
2 (clinically acceptable)	Rough surface, cannot be refinished
3 (clinically unacceptable)	Deeply pitted surface, irregular grooves

**Table 2.** Modified United States Public Health Service (USPHS) Criteria.

	Premolars ( <i>n</i> )		Molars ( <i>n</i> )		Total
	Onlay	Overlay	Onlay	Overlay	
<b>Maxilla</b>	4	3	15	8	30
<b>Mandible</b>	5	4	15	13	37
<b>Total</b>	16		51		67

**Table 3.** Distribution of restored teeth in the maxilla and mandible.

Criteria	Baseline (N=67)		6 months (N=66)				1 year (N=65)				2 year (N=65)			
	0	1	0	1	2	3	0	1	2	3	0	1	2	3
<b>Anatomy</b>	67		66				64	1			62	3		
<b>Marginal adaptation</b>	67		62	4			59	4	2		58	4	3	
<b>Marginal discoloration</b>	67		58	8			55	8	2		54	7	4	
<b>Color match</b>	61	6	57	9			55	10			55	10		
<b>Surface roughness</b>	67		61	5			59	6			58	7		
<b>Caries</b>	67		66				65				65			

**Table 4.** Results of the clinical evaluation (modified USPHS scores, %) at baseline and at 6-month, and 1- and 2-year follow-up.

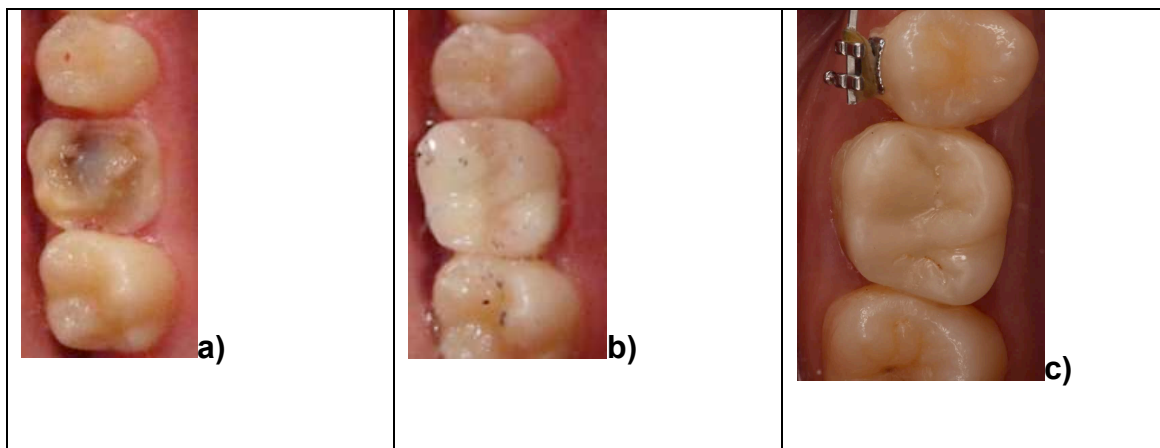
Variable (N=65)	15 days	6 months	1 year	2 years	p
	Median	Median	Median	Median	
	(Min-Max)	(Min-Max)	(Min-Max)	(Min-Max)	
<b>Anatomy</b>	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-1)	0.112
<b>Marginal adaptation</b>	0 (0-0) <sup>a</sup>	0 (0-1) <sup>b</sup>	0 (0-2) <sup>b</sup>	0 (0-2) <sup>b</sup>	<0.001
<b>Marginal discoloration</b>	0 (0-0) <sup>a</sup>	0 (0-1) <sup>b</sup>	0 (0-2) <sup>b</sup>	0 (0-2) <sup>b</sup>	<0.001
<b>Color match</b>	0 (0-1)	0 (0-1)	0 (0-2)	0 (0-2)	0.080
<b>Surface roughness</b>	0 (0-0) <sup>a</sup>	0 (0-1) <sup>b</sup>	0 (0-1) <sup>b</sup>	0 (0-1) <sup>b</sup>	0.001
<b>Secondary caries</b>	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	n.a.

**Table 5.** Frequency distribution of scores for the restorations based on the modified USPHS criteria. \*Different superscripts in one column indicate statistically significant difference ( $p < 0.05$ ).

Score	Color (%)	Surface Roughness (%)
Very good	58	80
Good	32	20
Satisfactory	10	-
Not satisfactory	-	-

**Table 6.** Frequency of scores for patient satisfaction (%) at the 2-year recall examination.

**Figures:**



**Figs. 1a-c** Representative photos of an overlay on the right 1<sup>st</sup> maxillary molar **a)** initial situation after endodontical treatment, **b)** baseline situation and **c)** at 2 years.